MAY 1 7 2000

K000155

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576-3544

Contact person: Kay A. Taylor

Date prepared: April 13, 2000

Predicate device

The Elecsys® Anti-Thyroid Peroxidase Antibody Test System is substantially equivalent to other devices legally marketed in the United States. We claim equivalence to the Immulite Anti-Thyroid Peroxidase Antibody (K963695).

Device name

Proprietary name:	Elecsys® Anti-Thyroid Peroxidase Antibody Test System
Common name:	Electrochemiluminescence Immunoassay, Anti-TPO
Classification name:	Thyroid Autoantibody Immunological Test System

Device description

The Elecsys® Anti-Thyroid Peroxidase Antibody Test System is based on a competitive immunoassay with streptavidin microparticles and electrochemiluminescence detection.

Results are determined using a calibration curve that is generated specifically on each instrument by a 2-point calibration and a master curve provided with the reagent bar code card.

1st incubation (9 min),
2nd incubation (9 min),

510(k) Summary, continued

Intended use

Immunoassay for the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma.

Indication for use

The anti-TPO determination is used as an aid in the diagnosis of autoimmune thyroid diseases.

Substantial equivalence

The Elecsys® Anti-Thyroid Peroxidase Antibody Test System is equivalent to other devices legally marketed in the United States. We claim equivalence to the Immulite Anti-Thyroid Peroxidase Antibody (Anti-TPO) Immunoassay (K963695).

Substantial equivalence – similarities

The following table compares the Elecsys® Anti-Thyroid Peroxidase Antibody Test System with the predicate device.

Feature	Elecsys® Anti-TPO Immunoassay	Predicate Device
Intended use	for the quantitative determination of antibodies to thyroid peroxidase in human serum and plasma.	for the quantitative measurement of antibodies against thyroid peroxidase (TPO) in serum and EDTA plasma
Indication for use	as an aid in the diagnosis of autoimmune thyroid diseases	as an aid in the clinical diagnosis of thyroid diseases
Sample type	human serum and plasma	human serum and plasma
Dilution performance	Autoantibodies are heterogenous and this may lead to non-linear dilution phenomena for certain individual samples.	Patient TPO antibodies and the antibodies used for calibrating the assay may differ in their binding properties. This may lead to deviations from strict dilutional parallelism for certain patient samples.
Traceability / Standardization	WHO 66/387	WHO 66/387

Substantial equivalence – differences

The following table compares the Elecsys® Anti-Thyroid Peroxidase Antibody Test System with the predicate device.

Feature	Elecsys® Anti-TPO Immunoassay	Predicate Device
Plasma type	Li-, Na-, NH_4- Heparin plasma K_3-EDTA plasma Na-Citrate plasma Na-Fluoride/Oxalate plasma	Heparin plasma EDTA plasma
Assay protocol	competitive assay	2-step sandwich assay
Detection protocol	Electrochemiluminescence	Enzyme Chemiluminescence
Instrument	Elecsys® 2010 and 1010 Immunoassay Analyzers	Immulite System
Measuring range	5 – 600 IU/ml	7-1000 IU/ml

Substantial equivalence – performance characteristics

The Performance characteristics of the Elecsys® Anti-Thyroid Peroxidase Antibody Test System and the predicate device are compared in the table below.

Feature	Elecsys® Anti-TPO Test System	Predicate Device
Intra-assay precision (%CV)	Human sera: 7.0% at 15.3 IU/ml 2.5% at 113 IU/ml 4.2% at 269 IU/ml	Serum samples: 4.3% at 54 IU/ml 3.5% at 185 IU/ml 5.6% at 825 IU/ml
	Controls: 5.6% at 25.9 IU/ml 3.4% at 112 IU/ml	
Inter-assay precision (%CV)	Human sera: 24.4% at 12.4 IU/ml 9.2% at 109 IU/ml 7.1% at 308 IU/ml	Serum samples: 10.5% at 57 IU/ml 8.7% at 183 IU/ml 7.8% at 345 IU/ml 10.5% at 619 IU/ml
	Controls: 13.2% at 25.4 IU/ml 7.6% at 116 IU/ml	
Analytical sensitivity	5 IU/ml	7 IU/ml
Limitations	• No interference from bilirubin up to 66 mg/dL • No interference from hemoglobin up to 1.5 g/dL • No interference from triglycerides up to 2100 mg/dL • No interference from biotin up to 60 ng/mL • No interference from rheumatoid factor up to 1500 U/mL	• No interference from bilirubin • No interference from hemoglobin (hemolyzed samples may indicate mistreatment of a specimen; the results should be interpreted with caution) • No interference from lipemia

Substantial equivalence – performance characteristics

The Performance characteristics of the Elecsys® Anti-Thyroid Peroxidase Antibody Test System and the predicate device are compared in the table below.

Feature	Elecsys® Anti-TPO Test System	Predicate Device
Method Comparison	Elecsys Anti-TPO on the Elecsys 2010 (Y) with the DPC Immulite Anti-TPO (X): Passing-Bablok- $Y = 0.77x + 2.94$, $r = 0.899$	DPC Immulite Anti-TPO compared to immunometric enzyme immunoassay. Relative sensitivity = 100% Relative specificity = 95.6%
Calibration frequency	Elecsys® 2010: • with every new reagent kit • after 4 days (same kit) Elecsys® 1010: • with every new reagent kit • using the same kit: after 4 days (20-25°C) after 3 days (25-32°C)	• with every new lot • after 2 weeks using the same lot

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 7 2000

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
Indianapolis, Indiana 46250-0457

Re: K000155
Trade Name: Elecsys® Anti-Thyroid Peroxidase Antibody Test System
Regulatory Class: II
Product Code: JZO
Dated: April 13, 2000
Received: April 14, 2000

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K000155

Device Name: Elecsys® Anti-Thyroid Peroxidase Antibody Test System

Indications For Use: For the in vitro quantitative determination of antibodies to thyroid peroxidase in human serum and plasma as an aid in the diagnosis of autoimmune thyroid diseases.

Peter E. Maheri

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000155

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)